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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------|
| 10/007,047 | 12/06/2001 | Theodora Ross | UM-06692 | 6232 |
| 72960 | 7590 | 11/01/2007 | | |
| Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711 | | | EXAMINER FETTEROLF, BRANDON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/01/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/007,047 | Applicant(s) ROSS ET AL. | |
| | Examiner Brandon J. Fetterolf, PhD | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 29, 84-86, 91-93 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 84-86 and 91-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 29 and 95 is/are rejected.
- 7) ☒ Claim(s) 25-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to the Amendment

The Amendment filed on 9/26/2007 in response to the previous Non-Final Office Action (5/17/2007) is acknowledged and has been entered.

Claims 24-27, 29, 84-86, 91-93 and 95 are currently pending.

Claims 84-86 and 91-93 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 24-27, 29 and 95 are currently under consideration.

Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 29 and 95 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of characterizing prostate cancer in a patient already diagnosed with prostate cancer by detecting the presence or absence of HIP1 in biopsy tissue with a nucleic acid probe configured to hybridize to a HIP1 nucleic acid sequence consisting of the nucleic acid sequence of SEQ ID NO: 1, wherein the absence of HIP1 in said sample is indicative of PSA non-recurrence and/or recurrence free survival, does not reasonably provide enablement for a method of characterizing prostate cancer in a patient already diagnosed with prostate cancer by detecting the presence or absence of HIP1 in a sample with a nucleic acid probe configured to hybridize to a HIP1 nucleic acid sequence consisting of the nucleic acid sequence of SEQ ID NO: 1, wherein the absence of HIP1 is indicative the PSA recurrence or recurrence free survival. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the prior office action.

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In response to this rejection, Applicants assert that claim 24 has been amended to include the elements of the absence of HIP1 being indicative of PSA recurrence or recurrence free survival. Thus, Applicants contend that as stated by the Examiner (see above), the specification is enabling for such a claim.

The arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner acknowledges and appreciates Applicants amendments to Claim 24 so as to recite the elements of the absence of HIP1 being indicative of PSA recurrence or recurrence free survival. However, the Examiner recognizes that the specification only appears to be enabling for detecting the presence or absence of HIP1 in a biopsied tumor tissue sample for the reasons set forth above; and therefore, is not commensurate in scope with the currently amended claims which include any and/or all samples.

Conclusion

Claims 25-26 appear to be free of the prior art, but are objected to as being dependent from a rejected independent claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF

A handwritten signature in black ink, appearing to read "Brandon Fetterolf, PhD", with a stylized flourish at the end.